

September 24, 2018

VIA E-MAIL FILING

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems

The American Association of Hip and Knee Surgeons (“AAHKS”) appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (“CMS”) on its hospital outpatient prospective payment system (“OPPS”) and ambulatory surgical center (“ASC”) payment system proposed rule for calendar year 2019 (hereinafter referred to as “CY 2019 OPPS proposed rule” or “proposed rule”).

AAHKS is the foremost national specialty organization of more than 3,600 physicians with expertise in total joint arthroplasty (“TJA”) procedures. Many of our members conduct research in this area and are experts on the evidence based medicine issues associated with the risks and benefits of treatments for patients suffering from lower extremity joint conditions. AAHKS is guided by its three principles:

- Payment reform is most effective when physician-led;
- The burden of excessive physician reporting on metrics detracts from care; and
- Patient access, especially for high risk patients and physician incentives must remain a focus.

Our comment focus on the following provisions of the FY 2019 OPPS proposed rule:

I. Proposed Changes to the Inpatient Only List (IPO) – Sec. IX.B

CMS solicited comments as to whether CPT code 01402, “Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty”, should be removed from the inpatient only (“IPO”) list and whether the code meets the five criteria used by CMS to identify procedures that should be removed. The five criteria are: (1) Most outpatient departments are

equipped to provide the services to the Medicare population; (2) The simplest procedures described by the code may be performed in most outpatient departments; (3) the procedure is related to codes that we have already removed from the IPO list; (4) a determination is made that the procedure is being performed in numerous hospitals on an outpatient basis; and (5) A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by is for addition to the ASC list. CMS seeks comment on whether CPT code 01402 meets criteria 3 and 4.

AAHKS Comment:

AAHKS appreciates the opportunity to discuss the removal of CPT code 01402 from the IPO list. CPT code 01402 certainly is related to 27447 which was removed from the IPO list effective in 2018. Further, the procedure is indeed being performed in hospitals on an outpatient basis. However, as we shared with CMS when it was considering removing total knee arthroplasty (“TKA”) from the IPO list, a more relevant factor is whether the procedure in question is being performed in numerous hospitals on *Medicare beneficiaries* on an outpatient basis.

As AAHKS explained in prior comment letters, TKA and its accompanying anesthesia can be performed in a hospital outpatient setting with careful patient selection and education, tailored anesthetic techniques, and good medical care. Ideally, TKA and associated anesthesia procedures would share the same IPO list status, but this proposal must be considered in relation to provider experience in 2018 with TKA since its removal from the IPO list and the application of the 2-midnight rule to it. In light of the continued confusion among providers as to CMS’s policy towards TKA, CMS should carefully consider whether the move will exacerbate confusion over the physician’s role in determining the appropriate admission status for TKA.

Please see the following section for an analysis of the ongoing physician and hospital confusion over CMS policy towards TKA admission status and new reports by physicians of the resulting chaos.

II. Ongoing Impacts from the Removal of TKA from the IPO List – Sec.IX

a. Removal of TKA from IPO List and AAHKS Comments in 2017

Following public notice and comment on the 2018 Medicare OPSS Proposed Rule, CMS finalized its proposal to remove TKA from the Medicare IPO list, effective January 1, 2018, allowing the procedure to be reimbursed as an outpatient or inpatient procedure.¹ CMS’s rationale is its stated belief that TKA now satisfies CMS’s previously established criteria for removing a procedure from the IPO list. Namely, (1) Most outpatient departments are equipped to perform TKA for Medicare beneficiaries; (2) The simplest procedure described by the code

¹ 82 FR 52522 (Nov. 13, 2017).

may be performed in most outpatient departments; and (3) The procedure is already being performed in numerous hospitals on an outpatient basis.²

AAHKS commented on CMS's proposal in the 2018 Medicare OPPTS Proposed Rule, stating that "in a setting with excellent patient selection and education, tailored anesthetic techniques, well done surgery, good medical care, and exceptional post-operative care coordination, it may be clinically appropriate for some Medicare beneficiaries to have the option of a TKA procedure as a hospital outpatient."³ Further, CMS stated that it expects providers to develop evidence-based patient selection criteria to identify candidates for outpatient TKA, and we responded that when surgeons are free from external pressures to make a judgment, in the best interests of the patient, on the appropriate site for surgery, such criteria will be followed.

b. Critical Interaction Between TKA and the "2-Midnight Rule"

i. Application of 2- Midnight Rule through Removal of TKA from the IPO List

By removing TKA from the IPO List, the procedure becomes subject to the Medicare "2-midnight rule,"⁴ under which, in general, if an admitting physician expects a beneficiary to require hospital care that spans at least 2 midnights and admits the beneficiary based on that expectation, the admission is appropriate for payment as an inpatient procedure under the inpatient prospective payment system ("IPPS"). Otherwise, the admission is likely to be considered, and reimbursed as, an outpatient procedure.

ii. Trend of TKA Clinical Advances Appear to Place a Significant Volume of the Procedure in a 2-Midnight Rule "Gray Area"

On its face, the 2-midnight rule is difficult to apply consistently to TKA because many of the TKAs performed on Medicare beneficiaries span slightly less or slightly more than 2 midnights. Since the inception of TKA, there have been many millions of patients who have been admitted to hospitals for their post-surgical care. These patients traditionally stayed in the hospital for 3-5 days and were often discharged to an inpatient rehabilitation or skilled nursing setting following their inpatient admission.

Until quite recently, the percent of patients who were institutionalized for over ten days, in hospital and in post-acute care, approached 50 percent. Patients who were more robust, had few medical comorbidities, and/or who had reliable social support were more likely to be discharged to home with home care. A number of clinical advances have made the care of patients facing TKA safer and more efficient. These include, among others, better pain management, opioid sparing protocols, better blood management protocols, improved surgical techniques, improved patient preparation and selection for surgery, improved patient and family

² See *id.*

³ AAHKS Comment Letter on 2018 Medicare OPPTS Proposed Rule, pg. 2 (Sept. 11, 2017)

⁴ Procedures on the IPO List are not subject to the 2-midnight rule.

education and engagement, and better infection prevention strategies. Hospitals and physicians have also invested significant time and resources into preoperative evaluation and treatment of modifiable risk factors, use of care navigators, longer coverage by physical therapists in order to help facilitate discharge, etc.

Consequently, patients are now convalescing more quickly following TKA and are finding it easier to return to their homes more reliably. Rather than being away from home for 10-14 days, as in the recent past, many can receive resource intensive interventions that span 1 to 3 days as an inpatient and can then be ready to safely continue their recovery in a non-clinical setting. This has been a great advance for patients and it would be unfortunate if the result of these advances is to drive Medicare beneficiaries into an outpatient setting when it is not clinically appropriate.

iii. Exceptions Exist to the 2-Midnight Rule for “Practitioner Judgment”

While the potential for earlier discharges are an advance for Medicare beneficiaries, it does not automatically follow that all Medicare TKA admissions that span less than 2 midnights are clinically appropriate for outpatient admission. First, as CMS notes, the 2-midnight rule is not a hard and fast rule, but exists “to provide *guidance* on when an inpatient admission would be appropriate for payment under Medicare Part A.”⁵

Second, recognizing the need for exceptions to accommodate a physician’s clinical judgment about the most appropriate site of care for a beneficiary, CMS implemented an exception standard to the 2-midnight rule that states: “Where the admitting physician expects a patient to require hospital care for only a limited period of time that does not cross 2 midnights, *an inpatient admission may be appropriate* for payment under Medicare Part A *based on the clinical judgment of the admitting physician* and medical record support for that determination.”⁶

The role of clinical judgment by the practitioner is of utmost importance in the novel area of outpatient TKA. The peer-reviewed literature contains examples of case series from select institutions with selected patient populations that have been able to perform TKA in the outpatient setting with attendant same day discharge. However, generalizing this experience to a broader population of patients and providers should be done with caution, as these institutions may have specific characteristics, including robust outpatient surgery programs with extensive experience, elements and pathways that enable early discharge in the outpatient setting.

⁵ 82 FR 52,523 (Nov. 13, 2017) (emphasis added).

⁶ 42 C.F.R § 412.3(d)(3) (emphasis added). *See also*, Medicare Program Integrity Manual Ch. 6 § 6.5.2 (E)(3), “For hospital stays that are expected to span less than 2 midnights, an inpatient admission may be payable under Medicare Part A on a case-by-case or individualized basis if the medical record supports the admitting physician/practitioner’s judgment that the beneficiary required hospital care on an inpatient basis despite the lack of a 2-midnight expectation”; and 82 FR 52,532 (Nov. 13, 2017), “If the physician expects the beneficiary to require hospital care that spans at least 2 midnights and admits the beneficiary based upon that expectation, the case is appropriate for payment under the IPPS.”

iv. CMS's Stated Policy is that the 2-Midnight Rule Should Cause Minimal Change in Current TKA Admission Status

We appreciate that the exception for practitioner judgment exists to protect the many Medicare beneficiaries for whom the TKA procedure is not expected to span more than 2 midnights but for whom an outpatient admission is not clinically appropriate. CMS explicitly notes, notwithstanding the 2-midnight rule,

We continue to believe that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment ***made by the physician based on the beneficiary's individual clinical needs and preferences*** and on the general coverage rules requiring that any procedure be reasonable and necessary.⁷

This practitioner judgment exception policy, combined with the fact that TKA is *not* a minor surgical procedure, accounts for CMS's statements that the beneficiaries able to receive a TKA on an outpatient basis are only "a subset of Medicare beneficiaries."⁸ Similarly, CMS "do[es] not expect a significant volume of TKA cases currently being performed in the hospital inpatient setting to shift to the hospital outpatient setting as a result of removing [TKA] from the IPO list."⁹ Therefore, the application of CMS guidance and policy statements related to the 2-midnight rule leads to the following conclusions: (1) for future TKAs that are expected to span more than 2 midnights, there is no change in policy related to inpatient admission status; (2) for future TKAs that are expected to span more than 24 hours, but less than 2 midnights, the practitioner judgment exception policy exists in order to allow the physician to select the most appropriate care setting base on the beneficiary's individual clinical needs.¹⁰

v. Apparent Inconsistencies Driving Confusion

We note, however, some apparent inconsistencies in CMS guidance that lies behind provider confusion. On the one hand, CMS statements imply that inpatient status will be the standard status for TKA for Medicare beneficiaries. As noted above, CMS "do[es] not expect a significant volume of TKA cases currently being performed in the hospital inpatient setting to shift to the hospital outpatient setting as a result of removing [TKA] from the IPO list."¹¹ Also, CMS expects providers will develop patient selection protocols to "appropriately *identify these patients . . . who are able to receive this procedure safely on a hospital outpatient basis.*"¹² This implies that, regardless of the 2-midnight rule, CMS considers the standard TKA status to be

⁷ 82 FR 52,523 (emphasis added).

⁸ 82 FR 52,524.

⁹ *Id.*

¹⁰ There are varying estimates among providers of what portion of Medicare TKA patient admissions span more than 24 hours, but less than 2 midnights.

¹¹ 82 FR 52534.

¹² *Id.* (emphasis added).

inpatient, while protocols will identify the patients who are an exception and may be safely treated as *outpatients*.

On the other hand, CMS's discussion of the 2-midnight guidance implies that CMS considers the standard TKA status for procedures that do not span 2 midnights to be *outpatient*, while only case-by-case exceptions may be made based on medical record support. Specifically, CMS states that "an inpatient admission is *generally* appropriate . . . if the physician . . . admits the patient based on the expectation that the patient will need hospital care that crosses at least 2 midnights."¹³ Further, CMS states that exceptions to the 2-midnight rule are only available "on a case-by-case basis."¹⁴ This means that, although the physiology of Medicare patients did not change from December 31, 2017 to January 1, 2018, nor did the standard of care, *inpatient status for a significant portion of TKA patients changed from being the only available option, to now quixotically being considered an exception that will only be granted on a case-by-case basis.*

c. Fee-for-Service Impacts of 2 Midnight Rule on Provider Experiences with TKA

i. Hospital Confusion

In spite of the CMS articulation of this policy in the preamble to the 2018 Medicare OPPS Final Rule, our members report an unprecedented amount of confusion and inconsistent interpretation by hospitals. Some hospitals are interpreting the policy consistent with the discussions above. Others, however, are implementing policies that they will not submit claims for any exceptions to the 2-midnight rule for TKA procedures that span more than 24 hours, but less than 2 midnights. Other hospitals have expressed to surgeons their expectation that most TKAs for Medicare beneficiaries will be performed on an outpatient basis.

This confusion could stem from several reasons. First, many hospitals likely did not read the 2018 Medicare OPPS Final Rule preamble language discussing exceptions for TKA procedures spanning less than 2 midnights. Second, some hospitals may have outdated policies on the 2-midnight rule. Our members have recently been confronted with hospital policies on the 2-midnight rule that are based upon procedures listed on the "rare and unusual exception" list, which CMS abandoned prior to 2016.

Third, in spite of CMS's 2 year suspension of Recovery Audit Contractor ("RAC") reviews of TKA admission status, many hospitals are very reluctant to make any exception to the 2-midnight rule based on prior experience with RACs. Some hospitals remain concerned over the possibility of retrospective reviews of TKA admission status after the 2 year period because they are not confident that the CMS policy on TKA exceptions to the 2-midnight rule has been thoroughly explained to RACs, Medicare Administrative Contractors ("MACs"), and other reviewers of claims.

¹³ 82 FR 52525 (emphasis added).

¹⁴ *Id.*

Fourth, hospitals have dealt with procedures coming off the IPO list and newly being subjected to the 2-midnight rule, but never for a procedure of such high volume. It is noteworthy that the annual volume of Medicare TKA procedures (approximately 306,000) is nearly 10 times greater than the volume of the next most common procedure removed from the IPO list prior to 2017 (code 22551 – arthrodesis), and nearly 6 times greater than the volume of the next most common procedure removed from the IPO list in 2017 (code 22842 – posterior segmental instrumentation). The volume is such that facilities lack the resources to devote to seeking the permitted case-by-case exceptions for all of them

Finally, TKA admission for the fee-for-service Medicare population has not previously been allowed, so the specialty societies have not yet developed clinical patient selection criteria for Medicare outpatient TKA. Therefore, physicians, facilities, and QIOs are unsure how to determine that “the documentation in the medical record supports the admitting physician’s determination that the patient requires inpatient hospital care” as opposed to outpatient care. Without such agreed upon clinical standards, there is a lack of any known standard for appropriate admission status review. We appreciate that CMS defers to clinicians to develop comprehensive patient selection protocols for outpatient TKA. While AAHKS is presently developing a position statement on clinically appropriate outpatient joint replacement, an industry-wide accepted standard does not yet exist.

ii. July 2018 AAHKS Member Survey that Confirms Ongoing Hospital Confusion¹⁵

- Have you been instructed by your hospital(s) to schedule fee for service Medicare patients needing a total knee as outpatients, and if they stay in the hospital for two nights they will change it to an inpatient admission?
 - 60% of 729 respondents answered YES. 40% answered NO.
- Have you been instructed by your hospital that unless the same patient stays two nights, they will remain an outpatient, regardless of services rendered?
 - 50% of 727 respondents answered YES. 50% answered NO.
- Have you been instructed by your hospital that the same patient can be made an inpatient even if less than two nights in the hospital?
 - 57% of 726 respondents answered NO. 43% answered YES.

iii. Impact on Patients are Reported by AAHKS Member Anecdotes

Our members have also shared with us the following personal examples of dealing with hospitals on this policy.¹⁶

¹⁵ See "Unintended Impact of the Removal of Total Knee Arthroplasty from the Center for Medicare and Medicaid Services Inpatient Only List," Yates AJ, Kerr J, Della Valle CJ, Huddleston JI, Froimson MI, [Forthcoming in *Journal of Arthroplasty*] (discussing survey results).

¹⁶ *Id.*

An ASA III risk level TKA patient with Parkinsons was denied inpatient status and while stable for 23 hour discharge, and voiding without retention signs, was sent home. I indicated ASA III risk and readmission risk, but under the effect of CMS pay practice the utilization review staff insisted he did not qualify for inpatient stay. In less than 1 week he was readmitted with severe urinary retention, bladder distention compressed iliac veins which likely directly contributed to bilateral femoral vein DVT and PEs. He survived anticoagulation and is now doing well. Readmissions cost staggering.

Another AAHKS physician shared the following:

The system where I practice has hired a consultant to review compliance. The consultant is of the opinion that very few, if any, Medicare TKRs qualify for in-patient status. In spite of the statements from AAOS, AAHKS, and, most importantly, CMS itself that the majority of TKRs will continue to be in-patient procedures, he has convinced our administrators to the contrary. Their review of traditional Medicare TKRs performed in the system since January 1 has determined that only 0.25% qualify for inpatient status. The system is now in the process of adjusting and resubmitting the bills for these patients . . . While the consultant understands that CMS will not retrospectively change the admission status for any TKR performed before 2020 through an audit, the consultant states that this is Medicare fraud as viewed by the OIG and the responsible party is the physician that wrote the admission order.

Another AAHKS physician shared the following:

At one of the largest multispecialty physician groups, multiple traditional Medicare patients received bills that they would not have otherwise received because their total knee was completed as an outpatient procedure instead of documented as an inpatient. One patient recently received a bill for \$20,000. This new ruling is creating confusion for the patients who have no idea what the bill will be until after the surgery is completed. The surgeon and the staff are not able to tell patients what the cost will be which is really unfair to our patients. The healthy patients are being penalized for being healthy.

Another AAHKS physician shared the following:

From my hospital system: "although the Federal Register has suspended the potential for RAC audits related to TKA, other agencies may still have the opportunity to review the TKA procedures against the guidelines and enforce the site of care requirements. The most notable of these would be our Medicare Administrative Contractor Novitas who is responsible for adjudicating payments made to our hospitals from the Medicare program, there are others as well."

Other members have shared the following:

- *Neither hospital I operate has any idea what to do here with regard to whether a TKA patient is inpatient or outpatient.*
- *We have absolutely no useful guidance for when to admit the patient or not. Our hospital has us start with the assumption that the patient will be an outpatient. I then use known risk factors to determine when I should admit. Usually when I reach 3 (obesity, OA, DM most commonly), I will admit. It does often prompt a call from hospital administration.*
- *The guidelines for outpt TKA for medicare is very confusing. The hospital was told that 10% of the medicare patients need to be outpatient. We've been told to schedule patients as outpatient if we know they are going home the next day.*
- *Our hospital is allowing them to come in as an inpatient, but then 90% are being converted to OBS status and then the patients are ending with bills for the services. Then the patient are calling the office screaming.*
- *Have been instructed that all patients over 70 can qualify as inpatients.*
- *Have been told changing status from outpatient to inpatient counts as a readmission against the surgeon.*

d. Opportunity for Medicare Advantage Plans to Deny Coverage of Inpatient TKAs

Also, we have shared with appropriate officials at CMS several concerning examples of Medicare Advantage ("MA") plans citing the removal of TKA from the IPO list as a basis to initially deny coverage for all TKA inpatient admissions. Absent appropriate oversight, some MA plans will continue to use any pretext based on a cursory reading of CMS policy to drive as many TKA procedures as possible to the outpatient setting.

In our member survey this summer 43% of 721 respondents reported that local MA plans had changed coverage policies to declare all/majority of TKAs to be scheduled as outpatient procedures.

e. Significant Alteration to Bundled Payment Metrics

We raised with appropriate officials within the Center for Medicare & Medicaid Innovation (“CMMI”) the impact this policy change has on our members participating in CMMI episode-based alternative payment models (“APMs”) that are based around DRG 469/470. Removing lower resource utilizing, healthier patients who are able to receive TKA procedures on an outpatient basis from the denominators for cost and quality performance metrics will impact most members’ ability to achieve quality goals and target pricing. The breadth of that impact will depend on whether hospitals recognize the exceptions to the 2-midnight rule laid out by CMS for TKA.

f. Readily Available CMS Options to Remedy Provider and Payer Confusion

i. AAHKS Proposed Program Guidance for TKA Transition Period

In June 2018, AAHKS shared with CMS its proposal to provide clear guidance to providers and compliance protection to hospitals and providers during a transition period of TKA as a possible outpatient procedure. Our proposal consists of a revision to the Program Integrity Manual so that, for the balance of 2018 and through 2019, Medicare contractors will conduct patient status reviews in accordance with a new category of exceptions to the 2 midnight benchmark.

Under the guidance, CMS would clearly restate its position that Medicare beneficiaries with less medical complexity who are able to receive this procedure safely on a hospital outpatient basis represent a subset of Medicare TKA patients. Further, that CMS does not expect a significant volume of TKA cases performed in the hospital inpatient setting prior to the removal from the IPO list to shift to the hospital outpatient setting as a result of removing TKA from the IPO list.

Under the guidance, a TKA, inpatient admission that spans 24 hours or more **is presumed** to be payable under Medicare Part A. This presumption would be rebuttable for less medically complex patients where factual and convincing evidence exists in the medical record to document that the patient is able to receive TKA safely on an outpatient basis, based on a number of factors, including the patient’s comorbidities, anticipated need for postoperative skilled nursing care, and other factors.

Medicare contractors would be instructed that when reviewing factual and convincing evidence of whether the patient is able to receive TKA safely on an outpatient basis, they shall consider factors that include, but are not limited to:

- The patient’s ability to ambulate independently
- The presence of adequate pain control through oral pain medications
- Patient toleration of oral intake
- Patient ability to void freely
- Patient’s hemodynamic stability
- Patient’s need for laboratory monitoring
- The absence of any medical condition that requires management in a hospital setting

ii. Promotion and Clarification of Preamble Statements to Hospitals, Surgeons, and MA Plans

A significant portion of the present confusion and conflicting interpretations could be mitigated through wider dissemination of the current CMS-stated intent of the policy. We request that CMS use the 2019 OPPS Final Rule to resolve the inconsistencies enumerated above on the interaction between the IPO List and the 2-midnight rule for TKA. Further, CMS can use the prior 9 months of its TKA claims history to confirm whether or not the policy in practice meets CMS’s expectations that there would not be “a significant volume of TKA cases currently being performed in the hospital inpatient setting [shifting] to the hospital outpatient setting as a result of removing [TKA] from the IPO list.”¹⁷

We request that CMS use its existing tools of the Medicare Learning Network, Open Door Forums, trade press outreach, and MAC issuances to ensure physicians, hospitals, and MA plans understand key elements of how the IPO list change and 2-midnight rule will impact TKA. Namely, that “the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary’s individual clinical needs and preferences.”¹⁸

CMS should make clear to MA plans that the IPO list should not be used to justify coverage policies that presume that the majority of MA enrollees would receive any TKA procedures as outpatients. Rather, MA plans are obligated to provide the same Parts A & B benefits to enrollees as are received by fee-for-service beneficiaries, and it is the expectation of CMS that outpatient TKA will be the exception and not the rule.

AAHKS appreciates your consideration of our comments. If you have any questions, you can reach Mike Zarski at mzarski@aaahks.org or Joshua Kerr at jkerr@aaahks.org.

¹⁷ 82 FR 52,524.

¹⁸ 82 FR 52,523.

Sincerely,



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